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DT17 Re PCT/PTO JUN 20 2002

DOCKET NO. MUR-032-USA-PO

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
H. CHONO, et al.

Serial No.: 10/031,747

Art Unit 1805

Filed: January 24, 2002

Examiner: To Be Assigned

For: Patch Formulation For External Use

REQUEST FOR CORRECTED FILING RECEIPT

Honorable Commissioner of
Patents and Trademarks
Washington, D.C. 20231


Sir:

Applicants' counsel is in receipt of the PTO Filing Receipt for the above-identified pending patent application, a copy of which is attached hereto. Upon verifying the accuracy of the data presented on the Filing Receipt it was noted that there are errors in the title for this invention which were introduced by the Patent Office. As evidenced by the attached copy of the Transmittal, Declaration and Power of Attorney, and first page of the original specification which contains the title, the title should read as follows: "Patch Formulation For External Use".

It is respectfully requested that the Patent Office records be corrected to reflect the correct title and that the undersigned be provided with a corrected Filing Receipt.

Respectfully submitted,

TOWNSEND & BANTA


Donald E. Townsend
Reg. No. 22,069

Date: June 20, 2002

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UNITED STATES PATENT AND TRADEMARK OFFICE
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APPLICATION NUMBER	FILING DATE	GRP ART UNIT	FILE FEE REC'D	ATTY. DOCKET NO.	DRAWINGS	TOT CLAIMS	IND CLAIMS
10/031,747	01/24/2002	1615	998	MUR-032- USA-PCT		26	2

CONFIRMATION NO. 8613

FILING RECEIPT



OC000000007803723

Townsend & Banta
1225 Eye Street NW Suite 500
Washington, DC 20005

Date Mailed: 04/09/2002

Receipt is acknowledged of this nonprovisional Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Customer Service Center. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

Applicant(s)

Hideharu Chono, Tsukuba-shi, JAPAN;
Toshiro Yamaguchi, Tsukuba-shi, JAPAN;
Hisakazu Kurita, Tsukuba-shi, JAPAN;
Tetsuro Tateishi, Tsukuba-shi, JAPAN;
Naruhito Higo, Tsukuba-shi, JAPAN;

Domestic Priority data as claimed by applicant

THIS APPLICATION IS A 371 OF PCT/JP00/04945 07/25/2000

Foreign Applications

JAPAN 11/212921 07/27/1999

Projected Publication Date: Not Applicable, filed prior to November 29, 2000

Non-Publication Request: No

Early Publication Request: No

Title

Patches for external use

Preliminary Class

**LICENSE FOR FOREIGN FILING UNDER
Title 35, United States Code, Section 184
Title 37, Code of Federal Regulations, 5.11 & 5.15**

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Office of Export Administration, Department of Commerce (15 CFR 370.10 (j)); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

TRANSMITTAL LETTER TO THE UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A FILING UNDER 35 U.S.C. 371

R-032-USA-PCT

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)

INTERNATIONAL APPLICATION NO.
PCT/JP00/04945INTERNATIONAL FILING DATE
July 25, 2000PRIORITY DATE CLAIMED
July 27, 1999

TITLE OF INVENTION

Patch Formulation For External Use

APPLICANT(S) FOR DO/EO/US Hideharu Chono, Toshiro Yamaguchi,
Hisakazu Kurita, Tetsuro Tateishi and Naruhito Higo

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. ☒ The US has been elected by the expiration of 19 months from the priority date (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
 - a. ☐ is attached hereto (required only if not communicated by the International Bureau).
 - b. ☒ has been communicated by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☒ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2))
 - a. ☒ is attached hereto.
 - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
 - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
 - b. ☐ have been communicated by the International Bureau.
 - c. ☒ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☐ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11 to 20 below concern document(s) or information included:

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☒ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☒ A **FIRST** preliminary amendment.
14. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
15. ☐ A substitute specification.
16. ☐ A change of power of attorney and/or address letter.
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825.
18. ☐ A second copy of the published international application under 35 U.S.C. 154(d)(4).
19. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
20. ☒ Other items or information: Claim For Priority

21. ☒ The following fees are submitted:**BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)):**

Neither international preliminary examination fee (37 CFR 1.482)
nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO
and International Search Report not prepared by the EPO or JPO \$1040.00

International preliminary examination fee (37 CFR 1.482) not paid to
USPTO but International Search Report prepared by the EPO or JPO \$890.00

International preliminary examination fee (37 CFR 1.482) not paid to USPTO
but international search fee (37 CFR 1.445(a)(2)) paid to USPTO \$740.00

International preliminary examination fee (37 CFR 1.482) paid to USPTO
but all claims did not satisfy provisions of PCT Article 33(1)-(4) \$710.00

International preliminary examination fee (37 CFR 1.482) paid to USPTO
and all claims satisfied provisions of PCT Article 33(1)-(4) \$100.00

ENTER APPROPRIATE BASIC FEE AMOUNT =

\$ 890.00

Surcharge of \$130.00 for furnishing the oath or declaration later than ☐ 20 ☐ 30
months from the earliest claimed priority date (37 CFR 1.492(e)).

\$ -0-

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	\$
Total claims	26 - 20 =	-6-	x \$18.00	\$ 108.00
Independent claims	2 - 3 =	-0-	x \$84.00	\$ -0-
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$280.00	\$ -0-

TOTAL OF ABOVE CALCULATIONS =

\$ 998.00

☐ Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above
are reduced by 1/2.

\$ -0-

SUBTOTAL =

\$ 998.00

Processing fee of \$130.00 for furnishing the English translation later than ☐ 20 ☐ 30
months from the earliest claimed priority date (37 CFR 1.492(f)).

\$ -0-

TOTAL NATIONAL FEE =

\$ 998.00

Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be
accompanied by an appropriate cover sheet (37 CFR 3.28; 3.31). \$40.00 per property +

\$ 40.00

TOTAL FEES ENCLOSED =

\$ 1038.00

Amount to be
refunded:

\$

charged:

\$

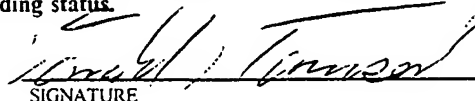
- a. ☒ A check in the amount of \$ 1038.00 to cover the above fees is enclosed.
- b. ☐ Please charge my Deposit Account No. _____ in the amount of \$ _____ to cover the above fees.
A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any
overpayment to Deposit Account No. 20-1424 duplicate copy of this sheet is enclosed.
- d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. Credit card
information should not be included on this form. Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR
1.137 (a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

TOWNSEND & BANTA
Suite 500, #50028
1225 Eye St., N.W.
Washington, D.C. 20005

phone: 202-682-4727



SIGNATURE

Donald E. Townsend

NAME

22,069

REGISTRATION NUMBER

As a below named inventor, I hereby declare that: my residence, post office address and citizenship are as stated below next to my name; that I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

PATCH FORMULATION FOR EXTERNAL USE

the specification of which is ☒ attached and/or ☐ was filed on as Application Serial No. and was amended on (if applicable)
☒ international (PCT) application No. PCT/JP00/04945 filed July 25, 2000 and as amended on (if any).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

COUNTRY	APPLICATION NUMBER	DATE OF FILING	PRIORITY CLAIMED UNDER 35 U.S.C. 119
JAPAN	11/212921	July 27, 1999	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
			<input type="checkbox"/> YES <input type="checkbox"/> NO

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

APPLICATION NUMBER	DATE OF FILING	STATUS (Patented, Pending, Abandoned)

I hereby appoint the following attorneys to prosecute this application and transact all business in the Patent and Trademark Office connected therewith: Law Offices of Townsend & Banta: Donald E. Townsend, Registration No. 22,069; ~~Teresa J. Banta, Registration No. 30,099~~; and Donald E. Townsend, Jr., Registration No. 43,198

Please address all correspondence to the Law Offices of Townsend & Banta, Suite 500, 1225 Eye Street, N.W., Washington, D.C. 20005

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

FULL NAME OF SOLE OR FIRST INVENTOR CHONO, Hideharu	INVENTOR'S SIGNATURE Hideharu Chono	DATE January 7, 2002
RESIDENCE c/o Tsukuba Laboratory of Hisamitsu Pharmaceutical Co., Inc., 25-11, Kannondai 1-chome, Tsukuba-shi, Ibaraki 305-0856 JAPAN	CITIZENSHIP JAPANESE	
POST OFFICE ADDRESS		
FULL NAME OF SECOND JOINT INVENTOR, IF ANY YAMAGUCHI, Toshiro	INVENTOR'S SIGNATURE Toshiro Yamaguchi	DATE December 27, 2001
RESIDENCE c/o Tsukuba Laboratory of Hisamitsu Pharmaceutical Co., Inc., 25-11, Kannondai 1-chome, Tsukuba-shi, Ibaraki 305-0856 JAPAN	CITIZENSHIP JAPANESE	
POST OFFICE ADDRESS		

Listing of Inventors Continued on Page 2 hereof. ☒ Yes ☐ No

Listing of Inventors Continued from Page 1 of Declaration and Power of Attorney for invention entitled:

PATCH FORMULATION FOR EXTERNAL USE

FULL NAME OF THIRD JOINT INVENTOR, IF ANY KURITA, Hisakazu	INVENTOR'S SIGNATURE <i>Hisakazu Kurita</i>	DATE December 27, 2001
RESIDENCE c/o Tsukuba Laboratory of Hisamitsu Pharmaceutical Co., Inc., 25-11, Kannondai 1-chome, Tsukuba-shi, Ibaraki 305-0856 JAPAN		CITIZENSHIP JAPANESE
POST OFFICE ADDRESS		
FULL NAME OF FOURTH JOINT INVENTOR, IF ANY TATEISHI, Tetsuro	INVENTOR'S SIGNATURE <i>Tetsuro Tateishi</i>	DATE December 27, 2001
RESIDENCE c/o Tsukuba Laboratory of Hisamitsu Pharmaceutical Co., Inc., 25-11, Kannondai 1-chome, Tsukuba-shi, Ibaraki 305-0856 JAPAN		CITIZENSHIP JAPANESE
POST OFFICE ADDRESS		
FULL NAME OF FIFTH JOINT INVENTOR, IF ANY HIGO, Naruhito	INVENTOR'S SIGNATURE <i>Naruhito Higo</i>	DATE December 26, 2001
RESIDENCE c/o Tsukuba Laboratory of Hisamitsu Pharmaceutical Co., Inc., 25-11, Kannondai 1-chome, Tsukuba-shi, Ibaraki 305-0856 JAPAN		CITIZENSHIP JAPANESE
POST OFFICE ADDRESS		
FULL NAME OF SIXTH JOINT INVENTOR, IF ANY	INVENTOR'S SIGNATURE	DATE
RESIDENCE	CITIZENSHIP	
POST OFFICE ADDRESS		
FULL NAME OF SEVENTH JOINT INVENTOR, IF ANY	INVENTOR'S SIGNATURE	DATE
RESIDENCE	CITIZENSHIP	
POST OFFICE ADDRESS		
FULL NAME OF EIGHTH JOINT INVENTOR, IF ANY	INVENTOR'S SIGNATURE	DATE
RESIDENCE	CITIZENSHIP	
POST OFFICE ADDRESS		
FULL NAME OF NINTH JOINT INVENTOR, IF ANY	INVENTOR'S SIGNATURE	DATE
RESIDENCE	CITIZENSHIP	
POST OFFICE ADDRESS		
FULL NAME OF TENTH JOINT INVENTOR, IF ANY	INVENTOR'S SIGNATURE	DATE
RESIDENCE	CITIZENSHIP	
POST OFFICE ADDRESS		

SPECIFICATION

PATCH FORMULATION FOR EXTERNAL USE

5 **Technical Field**

The present invention relates to a patch formulation for external use. In particular, the invention relates to a patch formulation for external use comprising a basic drug, an organic acid and an organic acid salt, having a good
10 percutaneous absorption property and good stability.

Background Art

Conventionally, various methods for administering drug have been known such as oral, rectal, intracutaneous or
15 intravenous administration, and among them oral administration is employed most widely. However, oral administration has some defaults, for example, that a drug is prone to a first pass effect in the liver, and that the blood level of a drug becomes transiently higher than that
20 required after it is administered orally. In addition, such adverse reactions as gastrointestinal disturbance, nausea, anorexia and so on have been often reported after oral administration. Furthermore, considering an increase in the number of patients with difficulty in deglutition in this aged
25 society, pharmaceutical formulations easier to take are required clinically. Therefore, patch formulations for external use have been actively developed and such products are also marketed, because they can eliminate these defaults